AMENDMENTS TO THE CLAIMS

1. (currently amended) A pharmaceutical composition for oral administration comprising PTH, wherein the *in vitro* release of PTH – when tested in a dissolution test of pharmacopoeia standard – is delayed with at least 2 hours and once the release starts, at least 90% w/w ~~such as, e.g., at least 95% or at least 99%~~ of all PTH contained in the composition is released within at the most 2hours.

2. (currently amended) A pharmaceutical composition according to claim 1, wherein –when tested in an in vitro dissolution test employing 0.1 N HCl equilibrated at 37 °C as the dissolution medium – at the most about 10% w/w ~~such as, e.g., at the most about 7.5% w/w, at the most about 5% w/w, at the most about 2.5% w/w, at the most about 1% w/w of PTH~~ contained in the composition is released 2 hours after start of the test.

3. (currently amended) A pharmaceutical composition according to claim 1 ~~or 2~~ for delivery of PTH to the small intestine and/or to the colon.

4. (currently amended) A pharmaceutical composition according to claim 1~~any of the preceding claims~~ for delivery of PTH to the jejunum.

5. (original) A pharmaceutical composition according to claim 4, wherein – when tested in an *in vitro* dissolution test employing a dissolution medium having a pH of about 6.8 and a temperature of about 37 °C – the following dissolution patterns of PTH are obtained (after start at pH 6.8):

at 15 min. approx. 20% w/w (limits 0-50 % w/w)
at 30 min. approx. 80% w/w (limits 25-100% w/w)
at 60 min. approx. 100 % w/w (limits 50-100% w/w)

6. (currently amended) A pharmaceutical composition according to claim 1 ~~any of claims 1-3~~ for delivery of PTH to ileum.

7. (original) A pharmaceutical composition according to claim 6, wherein – when tested in an *in vitro* dissolution test employing a dissolution medium having a pH of about 6.8 and a temperature of about 37 °C – the following dissolution patterns of PTH are obtained (after start at pH 6.8):

at 2 hours 30 min	approx. 20% w/w (limits 0-50 % w/w)
at 3 hours 30 min	approx. 80% w/w (limits 25-100% w/w)
at 4 hours 30 min	approx. 100% w/w (limits 50-100% w/w).

8. (currently amended)A pharmaceutical composition according to claim 1 ~~any of claims 1-3~~ for delivery of PTH to colon.

9. (original) A pharmaceutical composition according to claim 8, wherein – when tested in an *in vitro* dissolution test employing a dissolution medium having a pH of about 6.8 and a temperature of about 37 °C – the following dissolution patterns of PTH are obtained (after start at pH 6.8):

at 4 hours	approx. 20% w/w (limits 0-50 % w/w)
at 5 hours	approx. 80% w/w (limits 25-100% w/w)
at 6 hours	approx. 100 % w/w (limits 50-100% w/w).

10. (currently amended) A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~, wherein PTH is recombinant or of mammalian origin including human and is selected from full-length PTH (1-84) or its amino terminal fragment, PTH (e.g. PTH 1-34 etc).

11. (currently amended)A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~ further comprising a calcium-containing compound.

12. (original) A pharmaceutical composition according to claim 11, wherein – when tested in an in vitro dissolution test employing 0.1 N HCl equilibrated at

37 °C as the dissolution medium – the following dissolution pattern of calcium is obtained:

at 15 min. approx. 20% w/w (limits 0-50% w/w)

at 30 min. approx. 80% w/w (limits 25-100% w/w)

at 45 min. approx. 100 % w/w (limits 50-100% w/w).

13. (currently amended) A pharmaceutical composition according to claim 11 ~~or 12~~, wherein the calcium-containing compound is selected from the group consisting of bisglycino calcium, calcium acetate, calcium carbonate, calcium chloride, calcium citrate, calcium citrate malate, calcium cornate, calcium fluoride, calcium glubionate, calcium gluconate, calcium glycerophosphate, calcium hydrogen phosphate, calcium hydroxyapatite, calcium lactate, calcium lactobionate, calcium lactogluconate, calcium phosphate, calcium pidolate, calcium stearate and tricalcium phosphate.

14. (currently amended) A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~ further comprising a vitamin D (e.g. vitamin D_3).

15. (currently amended) A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~ comprising a further therapeutically and/or prophylactically active substance that is effective in bone related disorders.

16. (currently amended)A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~ further comprising an absorption enhancer.

17. (currently amended)A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~ further comprising a PTH-stabilizing agent.

18. (currently amended)A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~ in the form of a solid dosage form including tablets, capsules and sachets.

19. (currently amended)A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~ in the form of a multiple unit dosage form comprising a multiplicity of the same or different pellets or granules.

20. (currently amended)A pharmaceutical composition according to claim 1 ~~any of the preceding claim~~ comprising one or more of a first type of unit, the first type of unit comprising PTH, and the first type of unit having a layered structure of at least
i) an inner core
ii) a time-controlled layer surrounding the inner core,
iii) a film coating applied on the time-controlled layer, wherein the film coating is substantially water insoluble but permeable to an aqueous medium, and
iv) an outer layer of an enteric coating.

21. (original) A pharmaceutical composition according to claim 20, wherein the release of the active substance from the unit - when tested *in vitro* as an average of at least three determinations - is not more than about 10% w/w at a first pH value below about 4.0, and at a second pH value of from about 5.0 to about 8.0 the active substance is released in such a manner that - after a lag time of from about 0.5 to about 8 hours in which first time period not more than about 10% w/w of the active substance is released - at least about 50% w/w of the active substance contained in the unit is released within a second time period of not more than about 2 hours.

22. (original) A composition according to claim 21, wherein the release of the active substance from the unit– when tested *in vitro* – is not more than about 7.5% w/w ~~such as, e.g., not more than about 5% w/w, not more than about 2.5% w/w or not more than about 1% w/w~~ at the first pH value below about 4.0.

23. (original) A composition according to claim 21, wherein the first pH value is below about 3.5~~, such as, e.g., below about 3.0, below about 2.5, below about 2.0, below about~~ 1.5 or a pH value corresponding to that of 0.1 N HCl.

24. (currently amended)A composition according to claim 20 ~~any of claim 20-23~~, wherein the lag time is from about 1.0 to about 7 hours~~ such as, e.g., from about 1.5 to about 6 hours, from about 2.0 to about 5 hours or from about 2.5 to about 4.5 hours or from about 2.5 to about 4 hours~~.

25. (currently amended)A composition according to claim 20 ~~any of claim 20-24~~, wherein – after said lag time - at least about 60% w/w ~~such as, e.g., at least about 70% w/w, at least about 75% w/w, at least about 80% w/w, at least about 85% w/w, at least about 90% w/w, at least about 95% w/w or at least 99% w/w~~ of the active substance contained in the unit is released within the second time period of not more than about 2 hours.

26. (currently amended)A composition according to claim 21 ~~any of claims 21-25~~, wherein said second time period is not more than about 90 min~~ such as, e.g., not more than about 60 min, not more than about 50 min, not more than about 45 min, not more than about 40 min, not more than about 35 min, not more than about 30 min, not more than about 25 min, not more than about 20 min, not more than about 15 min, not more than about 10 min of not more than about 5 min~~.

27. (currently amended)A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~ provided with an enteric coating comprising an enteric polymer that has a pH cut off of at the most about 8.0~~ such as, e.g. in a range of from about 4.0 to about 7.5, in a range of from about 4.5 to about 7.0, from about 4.9 to about 6.9, from about 5.0 to about 6.5, from about 5.0 to about 6.3, from about 5.0 to~~

~~about 6.0, from about 5.0 to about 5.9, from about 5.0 to about 5.7, from about 5.0 to about 5.6 or from about 5.0 to about 5.5~~.

28. (currently amended)A pharmaceutical composition according to claim 20~~any of claims 20-27~~, wherein the core is selected from pharmaceutically acceptable beads, spheres, granules, granulates, and pellets.

29. (original) A pharmaceutical composition according to claim 28, wherein the lag time is controlled by the time it takes for the swellable layer to swell to such an extent that the film coating layer is disrupted or destructed.

30. (currently amended)A pharmaceutical composition according to claim 20~~any of claims 20-29~~, wherein the lag time is controlled by the thickness and/or composition of the time-controlled layer.

31. (currently amended)A pharmaceutical composition according to claim 20~~any of claims 20-30~~, wherein the lag time is further controlled by the thickness and/or composition of the film coating layer.

32. (currently amended)A pharmaceutical composition according to claim 20 ~~any of claims 20-31~~, wherein the disruption or destruction of the film coating layer iii) is substantially independent of pH.

33. (currently amended)A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~ in the form of a multiple unit composition.

34. (currently amended)A pharmaceutical composition according to claim 1~~any of claims 1-32~~ in the form of a single unit composition.

35. (currently amended)A pharmaceutical composition according to claim 1 ~~any of the preceding claims~~ comprising i) a PTH, ii) a calcium containing compound, and iii) a vitamin D.

36. (currently amended)A pharmaceutical composition according to claim 1 ~~any of claims 1-34~~ comprising i) PTH or a fragment, analog or derivative thereof, and ii) a vitamin D as active substances.

37. (original) A pharmaceutical kit comprising a first and a second component, the first component comprising PTH and the second component comprising a calcium-containing compound, wherein the *in vitro* release of PTH – when tested in a dissolution test of pharmacopoeia standard – is delayed with at least 2 hours and once the release starts, at least 90% w/w ~~such as, e.g., at least 95% or at least 99%~~ of all PTH contained in the composition is released within at the most 2 hours.

38. (currently amended)A pharmaceutical kit according to claim 37, wherein the first component comprising PTH comprises a composition as defined in claim 1 ~~any of claims 1-36~~.

39. (currently amended)A pharmaceutical kit according to claim 37 ~~or 38~~, wherein the two components are contained in the same or different container.

40. (currently amended)A pharmaceutical kit according to claim 37 ~~any of claims 37-39~~ further comprising instructions for use of the components.

41. (currently amended)A pharmaceutical kit according to claim 37 ~~any of claims 37-40~~ further comprising a third component comprising a second dose of a calcium-containing compound and with instruction for substantially simultaneous oral intake of the first and the second component followed by oral intake of the third

component after 2 hours or more ~~such as, e.g., 3 hours or more, 4 hours or more, 5 hours or more, 6 hours or more, 7 hours or more, or 8 hours or more~~.

42. (currently amended)A pharmaceutical kit according to claim 37 ~~any of claims 37-41~~ further comprising a vitamin D.

43. (original) A pharmaceutical kit according to claim 42, wherein vitamin D is included as one of the first or second components or as a separate component.

44-49. (cancelled)

50. (currently amended)A method for administering active substances to the small intestine or colon, the method comprises administering to a patient a sufficient amount of a pharmaceutical composition defined in claim 1 ~~any of claims 1-36, a kit as defined in any of claims 37-43 or a medicament as defined in any of claims 44-49~~.

51. (currently amended)A method for treatment or prevention of a bone related disorder including osteoporosis, the method comprising oral administration to a patient in need thereof a sufficient amount of PTH in a pharmaceutical composition as defined in claim 1 ~~any of claims 1-36, a kit as defined in any of claims 37-43 or a medicament as defined in any of claims 44-49~~.